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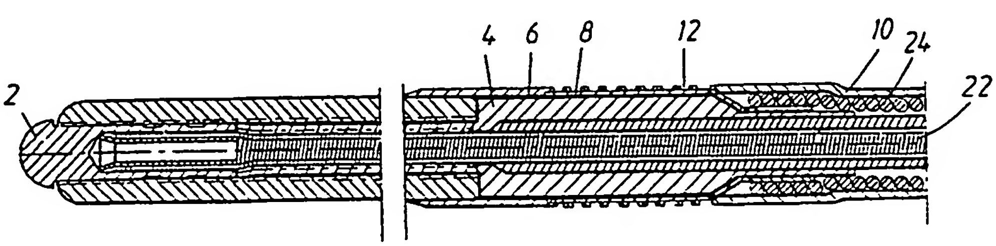

(57) Abstract

A multisensor system intended for controlling an implantable heart stimulator includes a piezoelectric sensor (4, 6, 8) adapted to be placed in the bloodstream of a living organism and comprising at least one electrode (8) adapted to be in electrical contact with said bloodstream. This electrode forms the measurement electrode of an oxygen pressure sensor.

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Sensor system

Technical field

The present invention relates to a multisensor system intended for controlling an implantable heart stimulator. The system includes a piezoelectric pressure sensor adapted to be placed in the bloodstream of a living organism and comprising at least one electrode adapted to be in electrical contact with said bloodstream.

Background Art

In today's pacemaker systems different physiological sensors are often used for rate control and diagnostics.

Thus, an electrochemical blood oxygen pressure sensor is described in Holmström et al., "Two years follow up on a pO_2-sensor controlled pacemaker: A comparative study in healthy and AV-node ablated dogs", Europace '97, 8th European Symposium on Cardiac Pacing, Athens, Greece, 8-11 June, 1997, pp. 477-481, and Holmström et al., "Long term in vivo experience of an electrochemical sensor using potential step technique for measurement of mixed venous oxygen pressure", Biosensors and Bioelectronics, 13(12), December 1998, pp 1287-1295. This partial blood oxygen pressure sensor - pO_2-sensor - includes an electrode set-up consisting of a working electrode, a reference electrode and a counter electrode, this last mentioned electrode being formed by the heart stimulator housing.

A piezoelectric pressure sensor adapted to be placed in the bloodstream of a living organism is disclosed in e.g. US-A-4,600,017, and in US-A-5,271,408 a system for blood flow measurements within vascular vessels or the heart is described. This system comprises two transducers, one of which consisting of piezoelectric segments mounted on the exterior surface of a catheter with outer electrodes adapted to be in electrical contact with the bloodstream.

With the aid of multisensor systems it is possible to extract more information about the body's need of cardiac output. Thus, a multisensor system for controlling a pacemaker is described in US-A-5,213,098. The multisensor system according to this US patent comprises two separated sensors, namely a ventricular or arterial blood pressure or flow sensor and a separate oxygen saturation sensor intended to be positioned in the coronary sinus. Such a multisensor system is, however, difficult to use and makes implantation complicated.

The purpose of the present invention is to provide a new, simple multisensor system including a piezoelectric pressure sensor and an oxygen pressure sensor, which is not suffering from the drawbacks of the above-mentioned prior art multisensor system.

Disclosure of the invention

This purpose is obtained by a multisensor system intended for controlling an implantable heart stimulator according to claim 1and which sensor system thus includes a piezoelectric pressure sensor adapted to be placed in the bloodstream of a living organism and comprising at least one electrode adapted to be in electrical contact with said bloodstream, and which sensor system is characterized in that said electrode forms the measurement electrode of an oxygen pressure sensor.

In this way existing electrode configurations of a heart stimulator are used for multisensor applications and a compact multisensor system of dual type is provided without changing the structure or mechanical properties of the stimulator electrode system.

Preferred embodiments are set forth in the dependent claims.

According to an advantageous embodiment of the sensor system according to the invention signal processing means are controlled to deliver as output signal said pressure signal

and said oxygen pressure signal from different selectable time windows of the cardiac cycle. Thus different time windows are selected for different kinds of measurements. The oxygen pressure measurement is a quick measurement and can preferably be performed in a measurement window after the QRS-complex.

In the preferred embodiment the piezoelectric pressure sensor comprises a supporting structure provided with a layer of piezoelectric material. According to anadvantageous embodiment of the sensor system according to the invention the supporting structure of the pressure sensor includes one of the materials of titanium, titanium alloy, titanium nitride, platinum, platinum alloy, niobium, niobium alloy, tantalum, tantalum alloy or carbon, since all these materials are biocompatible.

These materials may for instance be used as a conducting layer between the piezoelectric layer and a non-conducting supporting structure, for improving the conductivity between the piezoelectric layer and the supporting layer and/or for improving the adhesion of the piezoelectric layer to the supporting structure. For improving the adhesion a thin layer (2-3 atom layers) of titanium or chrome-nickel is preferred.

According to still other advantageous embodiments of the sensor system according to the invention, in which the piezoelectric element is provided with an outer electrically conducting layer which in its turn is covered by an electric insulation, a ring of said insulation is removed to form a ring-shaped measurement electrode of said oxygen pressure sensor or openings are made in said insulation to form said measurement electrode of said oxygen pressure sensor. This latter embodiment will increase the mechanical stability of the electrode.

According to yet other embodiments of the sensor system

provided for sensing the impedance between said measurement electrode and said reference electrode and supplying a corresponding impedance signal to said signal processing means for selectable separation of said pressure, oxygen pressure and impedance signals, and further depolarization sensing means can be provided for sensing depolarization signals picked up by said measurement electrode and supplying a corresponding depolarization signal to said signal processing means for selectable separation of said pressure, oxygen pressure, impedance and depolarization signals. Thus, in this way the multisensor system according to the invention is extended to include measurement of the parameters electrical impedance and depolarization without complicating or otherwise modifying the existing stimulator electrode configuration.

Brief Description of the Drawings

To explain the invention more in detail as examples chosen embodiments of the multisensor system according to the invention will now be described with a reference to the accompanying drawings on which

Figure 1 shows a longitudinal section through a part of a pacemaker lead provided with an embodiment of the multisensor system according to the invention,

Figure 2 shows in cross-section and longitudinal view a part of a lead designed to contain several parallel conductors,

Figure 3 shows in perspective view an embodiment of a dual sensor sensing element with a gold ring electrode as measurement electrode of a pO_2-sensor,

Figure 4 illustrates a lead provided with the sensor element in figure 3,

Figures 5-7 show different examples of pressure measurements performed on a dog with a dual sensor system as shown in Figure 1, and

Figure 8 shows the block diagram of an example of an implantable heart stimulator provided with a multisensor system according to the invention.

Description of preferred embodiments

Figure 1 shows a longitudinal section of a part of a lead for an implantable heart stimulator with a tip electrode 2 at the distal lead end. The lead is provided with a dual pressure and pO_2-sensor according to a first embodiment of the multisensor system according to the invention. The dual sensor thus comprises a supporting structure in the form of a conductive tube 4 covered with a layer of e.g., titanium alloy, titanium nitride, platinum, platinum alloy, niobium, niobium alloy, tantalum, tantalum alloy or carbon, which on its outer surface is covered with a layer or film 6 of a piezoelectric material, preferably a ceramic piezoelectric material. On the outer surface of the piezoelectric film 6 a layer 8 of a conductive material is applied. In this way the tube 4 and the layer 8 are forming electrodes for picking up the charge produced in the piezoelectric film 6, when it is subject to pressure variations, for producing a corresponding pressure signal. The lead further comprises an outer silicone rubber insulation 10.

In the embodiment shown in figure 1 circular openings 12 are formed in the insulating silicone rubber 10 to enable an electrochemical contact of the conductive layer 8 with blood. In this way the conductive layer 8 forms the measurement electrode for the pO_2-measurements.

The conductive supporting structure 4 forms the inner electrode of the pressure sensor and is electrically

connected to the inner conductor coil 22 of the lead in the contact area to the left of figure 1.

The outer conductive layer 8 which forms the outer electrode of the pressure sensor and the measurement electrode of the pO_2-sensor is in electrical contact with the outer conducting coil 24 of a lead in the contact area to the right in figure 2. Between these contact areas there is a sensing area where the rubber insulation 10 is partly removed to enable electrochemical contact between the conductive layer 8 and blood for the pO_2-measurement, as described above. The extension of each of the contact areas and the sensing area in the longitudinal direction of the lead can typically be about 3 mm. The thickness of the conducting layer 8 is typically 5-10 μm and this layer is made of e.g. gold or carbon.

The outer conducting layer 8 in the above described embodiment of the multisensor system according to the invention thus also forms the measurement or working electrode of a pO_2 sensor of the kind described in the above mentioned two articles by Holmström et al, "Two years follow up on a pO_2 sensor controlled pacemaker: A comparative study in healthy and AV-node ablated dogs, Europace '97, 8th European Symposium on Cardiac Pacing, Athens, Greece, 8-11 June, 1997, pp. 477-481, and "Long term in vivo experience on an electrochemical sensor using the potential step technique for measurement of mixed venous oxygen pressure", Biosensors and Bioelectronics, 13(12) December, 1998, pp. 1287-1295, with a reference electrode of carbon placed e.g. in the header of the pulse generator of a heart stimulator and the stimulator case being used as counter-electrode.

By breaking the electrode rubber insulation 10 in the form of circular openings 12 the mechanical stability of the conducting layer 8, serving as electrode, is increased. However, this design also introduces damping of the pressure signal.

To avoid this inconvenience a ring-shaped portion of the rubber insulation can be removed to expose a ring-shaped electrode 14, which is in contact with a tubular pressure sensing element 16, see figure 3. This pressure sensing element 16 is mounted in a lead 18 with the ring electrode 14 exposed for contacting the blood to form the measurement electrode of the pO_2-sensor, as illustrated as 20 in figure 4.

Figure 2 shows in perspective view and in cross-sections a part of alternative embodiments of the lead designed to contain several parallel conductors instead of multiple co-axially arranged spirals. This is a convenient way of making an increase of the number of conductors in the lead possible. In the figure tri-lumen 26, quadro-lumen 28 and heptal-lumen 30 embodiments are shown as examples. As the number of conductors can be easily increased in this embodiment two separate conductors can preferably be provided for the dual sensor according to the present invention described in connection with figure 1.

Figures 5-7 show examples of surface ECG's and invasive pressure signals recorded from the pressure sensor of a dual sensor as described above.

Figure 5 thus shows the surface ECG for a spontaneous heart rate of 125 beats per minute and the pressure signal from the sensor positioned in the centre of the right ventricle. The time scale is 100 ms per division. As appears figure 5 illustrates a very stable situation.

Figure 6 shows the corresponding signals recorded for a situation with DDD pacing with a rate of 120 beats per minute and the sensor positioned in the right atrium. In this case the dominating part of the pressure variation is the respiratory modulation.

Figure 7 illustrates a situation with DDD pacing with a rate of 115 beats per minute and the sensor being positioned in vena cava.

As appears from fig. 5-7 the pressure signal is a comparatively slowly varying signal, whereas the pO_2-measurement is a quick measurement, a measurement pulse of the order of 10 ms being used. Different time windows can therefore easily be selected for recording the pressure and the pO_2-signals respectively. The time window for the pO_2-measurement can suitably be synchronised to the detection of the QRS-complex while the pressure signal is recorded during the remaining part of the cardiac cycle. Of course, only pO_2-measurements or only pressure measurements can be performed for several consecutive cardiac cycles.

Figure 8 is a block diagram of a heart stimulator having pacemaker function and a multisensor system according to the present invention.

By an electrode, schematically shown at 32, implanted into the heart 34 of a patient, pressure signals and pO_2-signals are picked up as described above. These signals are supplied to a pressure sensor interface 36 and a pO_2-sensor interface 38. Corresponding sensed pressure and pO_2-values are fed to a sensor control unit 40 which is controlling the pacemaker functions by delivering corresponding sensor rate value and timing information to the pacemaker unit 42.

The sensor control unit 40 thus provides the interface to the different sensors and controls the measurement timing and weighting of the obtained sensor values. The pacemaker unit 42 provides in its turn the sensor control unit 40 with pacing status and timing information, like e.g. the detection of a spontaneous QRS-complex or if a stimulation pulse is

delivered to the heart 34, by the lead 32. The time for the pO_2-measurement can thus be controlled from the sensor control unit 40 to be synchronised to a time window connected to such an event, like the detection of a QRS, as explained above, while the pressure sensor can be active during the remaining part of the cardiac cycle. Of course, the multisensor system can be controlled to only measure the pressure signal or the pO_2-signal for a selected number of consecutive cardiac cycles.

The sensor control unit 40 can provide the pacemaker unit 42 with a sensor rate value for the control of the stimulation rate of the pacemaker. Thus the pO_2-signal can be used for the controlling of the rate responsive rate while the pressure can be used for capture verification for delivery of corresponding timing information to the pacemaker unit 42.

The reference electrode, preferably positioned in the header of the pacemaker, as mentioned above, and the counter electrode, preferably formed by the stimulator case for being locked to the stimulator battery ground, are schematically shown at 44 and 46 respectively.

By positioning the dual sensor described above in the right atrium of the heart 34 oxygen in mixed venous blood is measured by the pO_2-measurement. The pressure measurement in the right atrium can be used to provide information about non-optimal pacing indicated by abnormally high pressure peaks, for instance at a pacemaker syndrome situation in a VVI system. The pressure measurements can also be used for detecting spontaneous atrial activity and atrial fibrillation due to non-synchronous stimulation in the right ventricle.

By positioning the dual sensor in the right ventricle pressure timing information can be used to determine the correct time for delivering the next stimulation pulse, see

e.g. US,A, 5 417 715. A calculation of the pressure gradient dP/dt will then also give information about cardiac contractility.

By locating the described dual sensor in vena cava pressure peaks in vena cava, so called cannon waves, due to non-synchronous stimulation in the right ventricle, can be detected. The dual sensor can also be positioned in coronary sinus to measure coronary sinus pressure and oxygen content, which will be of value for the detection of e.g. ischemia. In general the multisensor system according to the invention will be of importance for detecting cardiac heart failures of patients having heart muscle ischemia and decreased pumping effect.

The multisensor system according to the invention can also comprise impedance and activity sensors. For the impedance measurement the same electrodes can be used as for the above described dual sensor. Thus the impedance can be measured between e.g. the measurement electrode 8 of figure 1 and the reference electrode 44 used for the pO_2-meaurements. The impedance can also be measured between e.g. the electrode tip 2, see figure 1, and the stimulator case, see 46 in figure 8.

The impedance signals are supplied to an impedance sensor interface 48 for delivery of corresponding sensor values to the sensor control unit 40 for use in the control of the pacemaker functions. Control signals are transferred in the opposite direction from the sensor control unit 40 to the impedance sensor interface 48 for controlling the impedance measurements.

In figure 8 an activity sensor in the form of a piezoelectric element 50 is also shown. The activity sensor 50 is also connected to the sensor control unit 40 via an activity sensor interface 52 for delivery of activity sensor values

for use in the control of the pacemaker functions. Control signals are transmitted from the sensor control unit 40 to the activity sensor interface 52 for controlling the activity measurements.

The activity sensor has normally a fast response to the start of a physical exercise and can thus provide a fast rate response. The impedance sensor is used for instance to extract the respiration minute volume and frequency.

The sensor control unit can comprise circuits of different complexity ranging from simple timing and multiplexing functions all the way to sensor value weighting using fuzzy logic or neural networks.

As shown in figure 8 the implanted heart stimulator comprises a telemetry unit 54 for communication with an external programmer 56, the skin of the patient being indicated by the dashed line 58. In this way the programmer 56 communicates via the telemetry unit 54 with the pacemaker unit 42 and the sensor control unit 40 for receiving and transmitting information and data related to the operation of the heart stimulator.

One example of a measurement scenario obtained with the multisensor system according to the invention could be that a low or intermediate activity is measured by the activity sensor, a high respiration frequency with small amplitude is obtained from impedance measurements, low pO_2-values forming an indication for rate increase are measured with the pO_2-sensor, and low contractility compared to rest values is detected from dP/dt obtained from blood pressure measurements. Such a scenario may be an indication of coronary insufficiency with an ongoing angina attack depending on heart muscle ischemia. In such a situation pacing should not

be increased since there is a risk to then end up in a more severe situation such as infarction or fibrillation.

It should be noted that, although the invention has been described in connection with a pressure sensor comprising a supporting structure covered with a piezoelectric layer it could also be used in connection with any piezoelectric sensor adapted to be in contact with the bloodstream and comprising at least one electrode adapted to be in electrical contact with said bloodstream.

Claims

1. A multisensor system intended for controlling an implantable heart stimulator, said system including a piezoelectric pressure sensor (4,6,8) adapted to be placed in the bloodstream of a living organism and comprising at least one electrode (8) adapted to be in electrical contact with said bloodstream characterized in that said electrode (8) forms the measurement electrode of an oxygen pressure sensor.

2. The sensor system according to claim 1, characterized in that signal processing means (40) are provided for selectable separation of an electric pressure signal received from said pressure sensor and an electric oxygen pressure signal received from said oxygen pressure sensor.

3. The sensor system according to claim 2, characterized in that said signal processing means (40) are controlled to deliver as output signal said pressure signal and said oxygen pressure signal from different selectable time windows of the cardiac cycle.

4. The sensor system according to any of the preceding claims, said sensor system being mounted in the lead (18,32) of an implantable heart stimulator, characterized in that a reference electrode (44) for said oxygen pressure sensor is provided on the stimulator casing.

5. The sensor system according to any of the claims 1 to 3, characterized in that the stimulator casing is forming a counter-electrode (46) for said oxygen sensor.

6. The sensor system according to any of the preceding claims, characterized in that said measurement electrode (8,14) comprises a gold or carbon layer.

7. The sensor system according to any of the preceding claims, characterized in that said piezoelectric pressure sensor comprises a piezoelectric element (6,16)

disposed on at least parts of the outer surface of an annular or tubular supporting structure (4).

8. The sensor according to claim 7, characterized in that said piezoelectric element is formed as a layer (6) of piezoelectric material on the outer surface of said supporting structure (4).

9. The sensor system according to claims 7 or 8, characterized in that said piezoelectric element is formed of a tube or ring of piezoelectric material, positioned around said supporting structure.

The sensor system according to any of the claims 7 to 9, characterized in that said supporting structure includes one of the materials of titanium, titanium alloy, titanium nitride, platinum, platinum alloy, niobium, niobium alloy, tantalum, tantalum alloy or carbon.

10. The sensor system according to any of the claims 8 to 11, characterized in that said measuring electrode is designed as a ring (14) around the outer surface of the piezoelectric element (16).

11. The sensor system according to any of the preceding claims, said piezoelectric element (6) being provided with an outer electrically conducting layer (8) which in its turn is covered by an electric insulation (10), characterized in that a ring of said insulation is removed to form a ring-shaped measurement electrode of said oxygen pressure sensor.

12. The sensor system according to any of the claims 1 to 11, said piezoelectric element (6) being provided with an outer electrically conducting layer (8) which in its turn is covered by an electric insulation (10), characterized in that openings (12) are made in said insulation (10) to form said measurement electrode of said oxygen pressure sensor.

13. The sensor according to any of the claims 7 to 12, said heart stimulator lead being a bipolar lead, characterized in that said piezoelectric element (6)

with associated electrodes (4,8) and possible supporting structure is mounted coaxially with the lead, between the inner and outer insulating layers of the lead.

14. The sensor system according to any of the claims 7 to 13, characterized in that said piezoelectric element is designed to exhibit circumferential sensitivity.

15. The sensor system according to any of the preceding claims, characterized in that impedance sensing means (48) are provided for sensing the impedance between said measurement electrode (8,14) and said reference electrode (44) and supplying a corresponding impedance signal to said signal processing means (40) for selectable separation of said pressure, oxygen pressure and impedance signals.

16. The sensor system according to any of the preceding claims, characterized in that activity sending means (50,52) are provided for sending the activity of the living organism and supplying a corresponding activity signal to said signal processing means (40) for selectable separation of said pressure, oxygen pressure, impedance, and activity signals.

17. The sensor system according to any of the preceding claims, characterized in that depolarization sensing means are provided for sensing depolarization signals picked up by said measurement electrode (8,14) and supplying a corresponding depolarization signal to said signal processing means (40) for selectable separation of said pressure, oxygen pressure, impedance, activity and depolarization signals.

18. A heart stimulator intended to be controlled by a multisensor system according to any of the preceding claims, characterized in that it includes said signal processing means.

Fig. 1

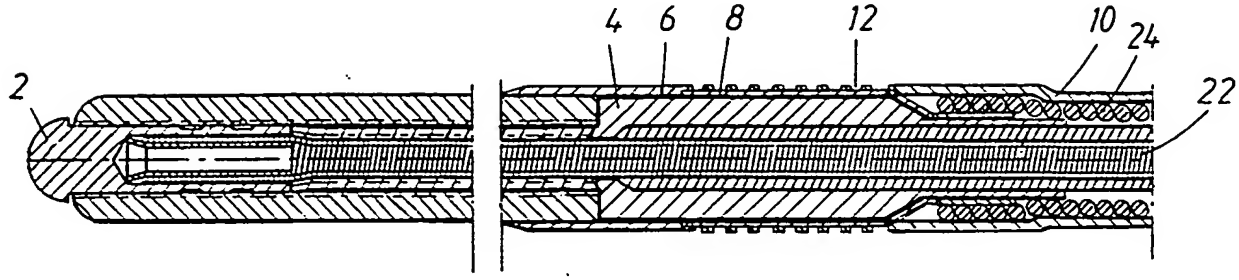


Fig. 2

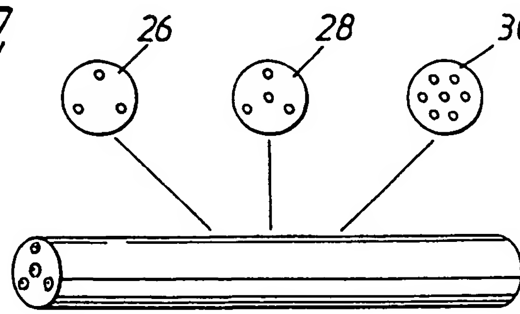


Fig. 3

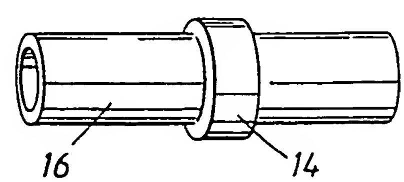


Fig. 4

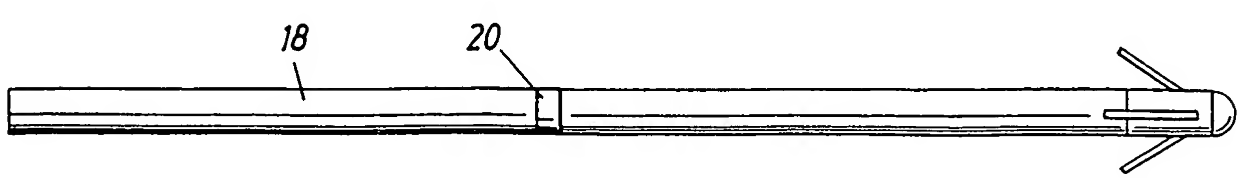


Fig. 5

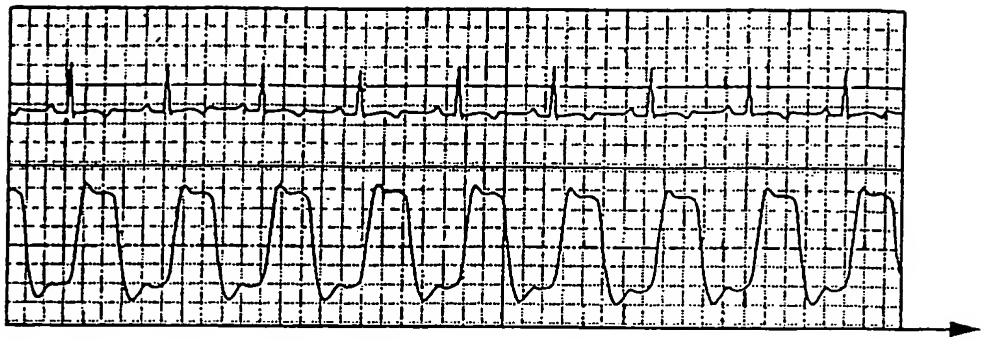


Fig. 6

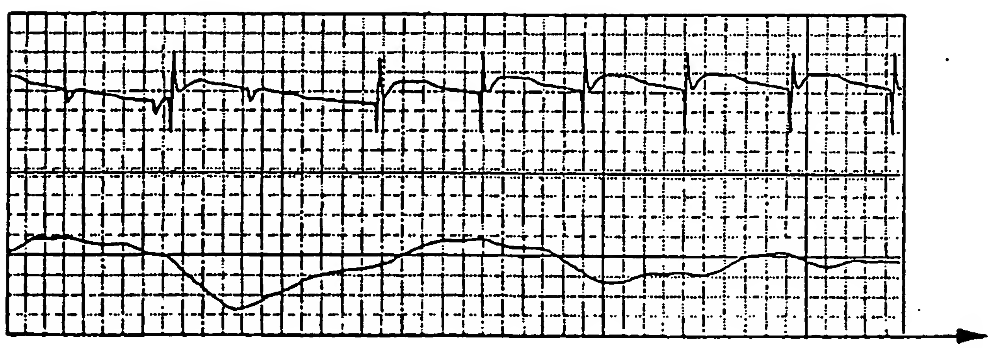
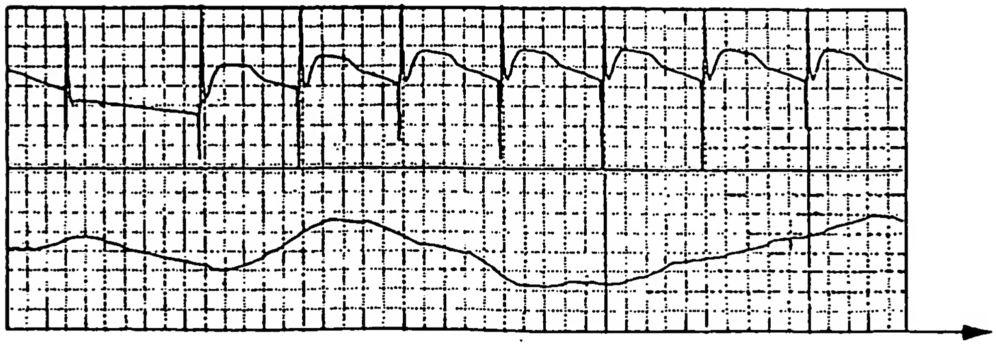


Fig. 7



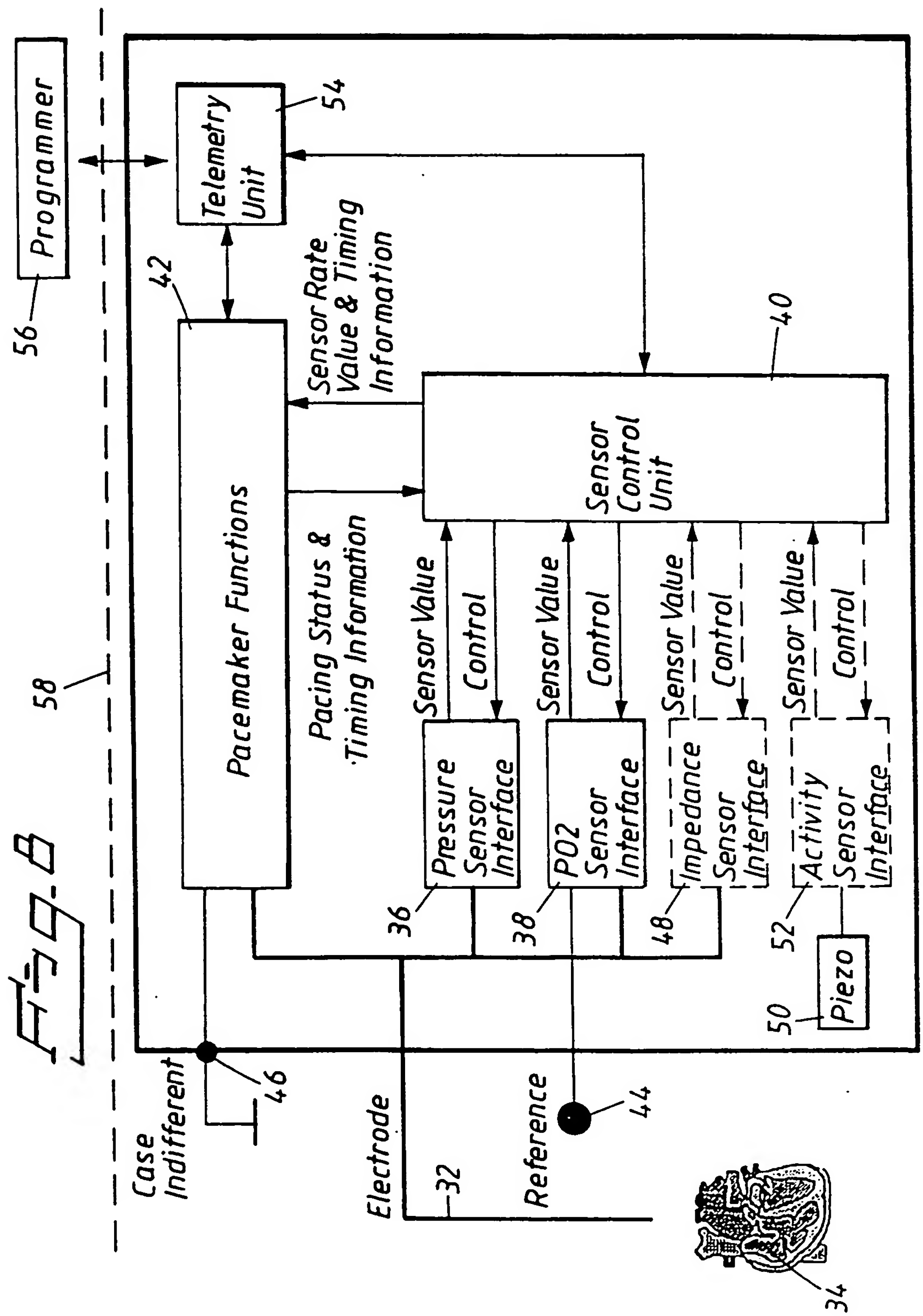

Programmer
56
58
Telemetry Unit
54
42
Pacemaker Functions
Sensor Rate Value & Timing Information
Pacing Status & Timing Information
Sensor Control Unit
40
Sensor Value
Control
Sensor Value
Control
Sensor Value
Control
Sensor Value
Control
Pressure Sensor Interface
36
PO2 Sensor Interface
38
Impedance Sensor Interface
48
Activity Sensor Interface
52
Piezo
50
Case Indifferent
46
Electrode
32
Reference
44
34

Fig. 8

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 00/00450

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61N 1/05 // A 61 N 1/365
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4860751 A (F.J. CALLAGHAN), 29 August 1989 (29.08.89), column 2, line 18 - line 53 --	1-18
A	US 5628777 A (S.B. MOBERG ET AL.), 13 May 1997 (13.05.97), abstract -- --------	1-18

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
22 June 2000	20 -07- 2000
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INTERNATIONAL SEARCH REPORT

Information on patent family members

02/12/99

International application No.
PCT/SE 00/00450

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 4860751 A	29/08/89	EP 0191404 A,B	20/08/86
US 5628777 A	13/05/97	AU 7331694 A	20/02/95
		US 5496361 A	05/03/96
		WO 9503086 A	02/02/95